Remarks

Claims 30-33 and 40 are pending in this application. Claims 1-29 and 34-39 were previously withdrawn in response to a restriction requirement, and claim 40 was previously added.

In the Office Action dated August 11, 2005, the Examiner has withdrawn the previous rejection of claims 30-32 as being unpatentable under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Maes et al., U.S. Patent No. 5,366,651.

Claims 30-33 and 40 stand rejected under 35 U.S.C. § 112 based upon the written description requirement. Claims 30-32 and 40 stand rejected under 35 U.S.C. § 102(b) based upon Reny et al., WO 89/09806. Claim 33 stands rejected under 35 U.S.C. § 103(a) over Reny et al., WO 89/09806. Claims 30-33 and 40 also stand rejected under 35 U.S.C. § 103(a) over Meyer et al., Patent No. 5,118,434, Maes et al., U.S. Patent No. 5,366,651, or Wood, U.S. Patent No. 4,455,248. Claims 30-33 and 40 have also been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-13 of copending Application No. 10/264,041; claims 1-10 of Application No. 10/347,900; claims 27-50 of Application No. 10/910,497; and claims 22-29 of Application No. 10/935,897. Applicants respectfully request reconsideration in view of the amendments to the claims and the remarks set forth below.

Applicants have cancelled claim 31.

Claim 30 has been amended to recite that the method of reducing the oral toxicity of the ethylene glycol based, non-aqueous fluid requires mixing an ethylene glycol based fluid with a polyhydric alcohol in an amount between 1 percent by weight and 30 percent by weight of the total weight of the polyhydric alcohol and ethylene glycol in the

resulting fluid. Claim 30 has been further amended to recite that the resulting fluid contains no additives requiring the presence of water to dissolve in the fluid or to enable the additive to function (i.e. water is required for the additive to dissociate or otherwise perform its function), and that the resulting fluid has an LD_{50} for oral toxicity in rats of at least 10,000 mg/kg.

Claim 40 has been amended to recite an embodiment of the invention in which propylene glycol is used as the polyhydric alcohol, and the resulting fluid contains between about 1 percent by weight and about 10 percent by weight propylene glycol.

Support for these amendments may be found in the specification at, for example, page 20, line 19 to page 24, line 8, and at page 26, line 5-7. No new matter is added.

As set forth in claims 30, 32-33 and 40 as amended, the present invention is directed to a method to reduce the oral toxicity of an ethylene glycol based, non-aqueous fluid. As described in the specification, the fluid may be used, for example, as a heat transfer fluid in internal combustion engines. A polyhydric alcohol that acts as an ADH enzyme inhibitor is added to the ethylene glycol based, non-aqueous fluid such that the concentration of the polyhydric alcohol is between 1 percent by weight and 30 percent by weight of the total weight of the ethylene glycol and the polyhydric alcohol in the resulting fluid. As recited in Claim 30 as amended, the fluid contains no additives that require the presence of water in the fluid to remain dissolved in the fluid, and the resulting fluid has an LD_{50} value for oral toxicity in rats of greater than 10,000 mg/kg. As described in the specification at pages 20-24, the inventors unexpectedly discovered that the addition of a polyhydric alcohol that acts as an ADH enzyme inhibitor, such as propylene glycol or glycerol, unexpectedly reduced the oral toxicity of the fluid to levels much lower than would be predicted based upon the oral toxicity of the individual fluids (note that a higher LD_{50} indicates lower oral toxicity, i.e. more material must be ingested

to cause a toxic effect). As shown in Fig. 3, in fluids containing 70% or more ethylene glycol (i.e. 30% or less propylene glycol or glycerol), the predicted LD_{50} in rats was about 6,000 mg/kg or less. The present inventors discovered that the addition of relatively low levels of a polyhydric alcohol such as propylene glycol or glycerol reduces the toxicity of ethylene glycol based fluids, rendering them much safer in storage and in use.

As recited in claims 32, 33 and 40, in certain embodiments of the invention, the ADH enzyme inhibitor may be propylene glycol or glycerol.

As described in the specification at, inter alia, pages 11-14 and as recited in the amended claims, the method of the present invention results in a non-aqueous ethylene glycol based fluid which is prepared without the use of water and is used without the addition of any water. Water is not used in the fluid as a mixing agent or as a means of heat transfer, and is only present, if at all, as an impurity. As described in the specification at, inter alia, pages 17-20, the heat transfer fluids of the mixtures described in the present application exhibit the necessary physical properties, such as, for example, viscosity and vapor pressure, to function effectively in most applications.

The amendments to claim 30 address the rejection under 35 U.S.C. § 112. The ranges for ethylene glycol and the polyhydric alcohol have been restated in a manner that is plainly set forth in the specification at the pages cited above.

The Rejections Under 35 U.S.C. §§ 102(b) and 103(a) Based Upon Reny

Reny, WO 89/09806, describes a heat transfer fluid containing alkylene glycols, corrosion inhibitor additives, phosphoric acid to buffer the pH of the fluid and up to 10 percent water. Although Reny states that the fluid may contain as little as 1 percent by weight water, the fluid described in Reny must contain sufficient water to maintain the phosphoric acid buffer in solution. All of the examples of the fluid and preferred

embodiments disclosed in Reny, including the example of a mixture of ethylene glycol and propylene glycol in Table 1, contain water added to the alkylene glycol and the addition of solutions of phosphoric acid. Reny does not disclose, or otherwise teach or suggest, a fluid that contains no additives that require the presence of added water in the fluid as recited in the claims as amended.

The Examiner states at page 5 of the Office Action that Reny describes a composition that contains no water at page 3, lines 1-15. In the passage cited by the Examiner, Reny merely describes some components of the composition rather than a complete composition. Reny states that the composition comprises "at least 90 weight percent of an alkylene glycol or a mixture of two or more alkylene glycols", but in the passage cited by the Examiner, Reny does not describe any specific ratios of alkylene glycols. Moreover, in the passage of Reny cited by the Examiner, Reny describes inclusion of a phosphoric acid buffer, which requires sufficient water to remain in solution. On page 5, line 28, Reny states that "The coolant composition of this invention is prepared by first dissolving up to 10 weight percent of water in the alkylene glycol." Thus, Reny states that added water is required in the composition.

Reny teaches that the phosphoric acid buffer must be added to the fluid unless the pH of the alkylene glycol mixture is within the pH range of 7-9. Page 5, lines 24-26. Although Reny states that some alkylene glycol mixtures may not require buffering, Reny does not identify any such mixtures. In the embodiments actually described by Reny, water and a phosphoric acid buffer are present. Therefore, Reny does not describe a non-aqueous fluid as defined in the specification comprising ethylene glycol and propylene glycol within the ranges recited in the claims and that does not contain any added water to dissolve additives in the fluid or to enable the additives to function in the fluid.

The Examiner also cites one of the examples provided in Reny at page 9. The example composition contained 30 parts propylene glycol, 70 parts ethylene glycol, and, purposefully, 1 part water. Accordingly, the fluid described on page 9 of Reny, although intended for use without *further* additions of water, necessarily contains enough added water to keep the required phosphoric acid dissolved and functioning.

In all of the embodiments of the composition described by Reny, the composition contains at least about 1% by weight water. Reny also states that the composition comprises *at least* 30 % by weight propylene glycol.

In the August 11, 2005 Office Action, the Examiner has rejected claims 30, 32 and 40 as anticipated by Reny. To anticipate a claim under 35 U.S.C. § 102(b), each and every element of the claimed invention must be found in a single prior art reference. MPEP § 2131. Reny does not describe a method for reducing the toxicity of an ethylene glycol based, non-aqueous fluid by adding an ADH enzyme inhibitor as recited in the amended claims. The fluids described by Reny do not describe at least the following limitations of claims 30, 32 and 40 as amended: (1) addition of a polyhydric alcohol, such as propylene glycol, to an ethylene glycol based, non-aqueous fluid in the proportions set forth in the claims as amended, and (2) a fluid that does not contain any added water or any additives requiring water to remain dissolved or otherwise function. Moreover, Reny does not describe a fluid containing as little as 1% by weight propylene glycol as recited in claims 32 and 40. Accordingly, for at least each of these reasons, Reny does not describe each and every element of claims 30, 32 and 40 as amended, and these claims are patentable over Reny under 35 U.S.C. § 102(b).

The Examiner has rejected claim 33 as obvious in view of Reny. Reny does not teach or suggest adding glycerol to an ethylene glycol based, non-aqueous fluid in any specific proportions, much less in the proportions recited in the claims as amended. Reny

does not recognize the problem of oral toxicity of ethylene glycol based heat transfer fluids, much less teach or suggest a solution to this problem. Reny merely states in a general way that ethylene glycol and other alkylene glycols may be combined, and Reny does not or suggest combining ethylene glycol with propylene glycol or glycerol in the ranges recited in the claims, which provide unexpectedly reduced oral toxicity. Reny is therefore insufficient to support a rejection under 35 U.S.C. § 103(a). See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP 2144.08.

Reny nowhere teaches or suggests combining glycerol with ethylene glycol to reduce the toxicity of the resulting fluid. At page 7 of the Office Action, the Examiner states that Reny suggests reducing the toxicity of an ethylene glycol based fluid by addition of a polyhydric alcohol such as glycerol. There is no such teaching or suggestion in Reny. Accordingly, for at least these reasons, the rejection of claim 33 as obvious in view of Reny should be withdrawn.

The Rejection Under 35 U.S.C. § 103(a) Based Upon Meyer

Claims 30, 32-33 and 40 stand rejected under 35 U.S.C. § 103(a) under Meyer, U.S. Patent No. 5,118,434. Meyer describes deicing solutions comprising alkylene glycols, water, corrosion inhibitors, and one or more polymeric additives. Meyer states at Column 2, lines 58-61 that the composition contains "up to 50 percent water" and preferably between 1 and 10 percent water by weight. The composition described by Meyer is intended to prevent precipitation of materials contained in the composition, and precipitation of materials contained in water that may be mixed with the composition.

The composition described in Meyer requires the presence of added water to maintain the additives described therein in solution. Indeed, Meyer states at Col. 2, lines

59-61 that the composition preferably contains between about 1 and 10 percent by weight water. As recited in the amended claims, and as described in the specification, the composition of the present invention is non-aqueous, which is defined in the specification as meaning that there is no added water, and that water is present only as an impurity. The only additives present in the fluids formed by the method of the present invention are soluble in ethylene glycol and the ADH enzyme inhibitor, such as propylene glycol or glycerol. Meyer does not teach or suggest a fluid that does not contain added water.

At page 8 of the Office Action, the Examiner correctly states that Meyer does not teach with sufficient specificity a method for reducing the toxicity of an ethylene glycol based fluid by the addition of a polyhydric alcohol such as propylene glycol or glycerol. The Examiner incorrectly states, however, that it would have been obvious to one skilled in the art to reduce the oral toxicity of an ethylene glycol based fluid because Meyer teaches or suggests reducing the oral toxicity by addition of a diol such as propylene glycol. Meyer does not recognize or discuss the problem of reducing the oral toxicity of ethylene glycol based fluids, much less describe, teach or suggest a method to reduce the toxicity of a non-aqueous ethylene glycol based fluid as recited in the new and amended claims. Moreover, Meyer does not describe, teach or suggest, combining ethylene glycol containing fluids with a polyhydric alcohol such as propylene glycol or glycerol in any specific proportions, much less the specific proportions recited in claims 30, 32-33 and 40, which resulted in a fluid having an unexpectedly large decrease in oral toxicity. Meyer is therefore insufficient to support a rejection under 35 U.S.C. § 103(a). See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP § 2144.08.

As shown, for example, in Fig. 3, the predicted LD_{50} in rats for the claimed combination of ethylene glycol and propylene glycol was about 6,000 mg/kg or less. As set forth in the specification at pages 24-27, the inventors discovered that the claimed compositions unexpectedly had an LD_{50} in rats of at least 10,000 mg/kg or more. Where as here a claimed range achieves unexpected results, the claimed range is patentable over the prior art. In re Woodruff, 919 F.2d 1575 (Fed. Cir. 1990); MPEP § 2144.05.

For at least these reasons, the claims as amended are not obvious under 35 U.S.C. § 103(a) in view of Meyers.

The Rejection Under 35 U.S.C. § 103(a) Based Upon Maes

Claims 30, 32-33 and 40 stand rejected under 35 U.S.C. § 103(a) based upon Maes, U.S. Patent No. 5,366,651. As noted by the Examiner on page 7 of the Office Action, Maes describes a fluid containing "*a* water-soluble liquid alcohol freezing point depressant" in anti-freeze compositions. Maes describes fluids containing only a single freezing point depressant, not a combination of glycols as recited in the amended claims. At col. 3, line 65 to col. 4, line 68, Maes states "The antifreeze formulations most commonly used include water and water soluble liquid alcohol freezing point depressants such as glycol and glycol ethers." In this sentence, Maes uses glycol in the singular and glycol ethers in the plural. In the sentence following, Maes provides a list of "glycol ethers" which can be employed. Throughout the specification, Maes describes antifreeze formulations containing a single glycol, indicating that only a single glycol is used in the formulation. Thus, Maes plainly describes the use of a single glycol, and Maes does not teach or suggest any combination of glycols, much less the combination and proportions recited in the claims. For at least this reason, in addition to the reasons set forth in Applicants' August 16, 2004 Response to Office Action in this case, applicants' maintain

that Maes does not describe, teach or suggest the combination of more than one glycol freezing point depressant for any reason, much less the addition of a second glycol to a fluid containing ethylene glycol to reduce the oral toxicity of the ethylene glycol-containing fluid as recited in the methods of claims 30, 32-33 and 40.

Even if Maes were somehow read to describe combinations of glycols, which Applicants maintain is incorrect, claims 30, 32-33 and 40 are patentable over Maes under 35 U.S.C. § 103. Maes does not describe, teach or suggest a method to reduce the toxicity of an ethylene glycol based, non-aqueous heat transfer fluid by addition of an ADH enzyme inhibitor such as propylene glycol as recited in the amended claims. Moreover, Maes does not teach or suggest combining an ethylene glycol based heat transfer fluid in any specific proportions with propylene glycol, much less in the proportions recited in claims 30, 32-33 and 40. As set forth in the specification, the present inventors discovered that adding an ADH enzyme inhibitor such as propylene glycol in the proportions recited in claims 30, 32-33 and 40 to an ethylene glycol based heat transfer fluid unexpectedly reduced the toxicity of the resulting fluid below the level that would have been predicted based on the properties of the individual fluids.

At page 8 of the Office Action, the Examiner correctly states that Maes does not teach with sufficient specificity a method for reducing the toxicity of an ethylene glycol based fluid by the addition of a polyhydric alcohol such as propylene glycol or glycerol. The Examiner incorrectly states, however, that it would have been obvious to one skilled in the art to reduce the oral toxicity of an ethylene glycol based fluid because Maes teaches or suggests reducing the oral toxicity by addition of a diol such as propylene glycol. Maes does not recognize or discuss the problem of reducing the oral toxicity of ethylene glycol based fluids, much less describe, teach or suggest a method to reduce the toxicity of a non-aqueous ethylene glycol based fluid as recited in the new and amended

claims. Moreover, Maes does not describe, teach or suggest, combining ethylene glycol containing fluids with a polyhydric alcohol such as propylene glycol or glycerol in any specific proportions, much less the specific proportions recited in claims 30, 32-33 and 40, which resulted in a fluid having an unexpectedly large decrease in oral toxicity. Maes is therefore insufficient to support a rejection under 35 U.S.C. § 103(a). See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP § 2144.08.

As shown, for example, in Fig. 3, the predicted LD_{50} in rats for the claimed combination of ethylene glycol and propylene glycol was about 6,000 mg/kg or less. As set forth in the specification at pages 24-27, the inventors discovered that the claimed compositions unexpectedly had an LD_{50} in rats of at least 10,000 mg/kg or more. Where as here a claimed range achieves unexpected results, the claimed range is patentable over the prior art. In re Woodruff, 919 F.2d 1575 (Fed. Cir. 1990); MPEP § 2144.05.

For at least these reasons, the claims as amended are not obvious under 35 U.S.C. § 103(a) in view of Maes.

The Rejection Under 35 U.S.C. § 103(a) Based Upon Wood

Claims 30, 32-33 and 40 also stand rejected based upon Wood, U.S. Patent No. 4,455,248. Wood describes an antifreeze composition for use in automotive cooling systems or other heat transfer services. Wood states that the composition "necessarily" contains sodium metasilicate. Col. 3, lines 27-55. Although Wood states that "the antifreeze may be formulated as a concentrate using little or no water", (col. 3, lines 7-8), the requirement that the fluid described by Wood contain sodium metasilicate necessitates the addition of sufficient water for the sodium metasilicate to dissolve and remain in solution, i.e. in order for the sodium metasilicate to function. As set forth in

the attached information sheet from the Occupational Safety & Health Administration, sodium metasilicate is not soluble in alcohols such as glycols, but is readily soluble in water. Accordingly, for at least this reason, Wood does not teach or suggest a heat transfer fluid composition as recited in claims 30, 32-33 and 40, which recite that the heat transfer fluid of the present invention contain no additives requiring the presence of water in the fluid.

Also, Wood does not teach or suggest a method to reduce the toxicity of a non-aqueous, ethylene glycol based heat transfer fluid as recited in claims 30, 32-33 and 40 as amended. Wood states that the antifreeze composition is used in the heat transfer service by diluting the composition with water. Col. 3, lines 16-22. Thus, Wood describes a method using an aqueous heat transfer fluid, which is plainly different from the non-aqueous heat transfer fluid as defined in the specification and recited in the claims as amended.

Moreover, although Wood generally states that mixtures of glycols may be used in the anti-freeze compositions described therein, Wood does not teach or suggest combining ethylene glycol and propylene glycol in any specific proportions, much less in the proportions recited in the amended claims. As described in the application, the present inventors unexpectedly discovered that adding relatively small amounts of propylene glycol to ethylene glycol unexpectedly resulted in a non-aqueous heat transfer fluid having substantially reduced toxicity. Wood does not teach or suggest combining ethylene glycol and propylene glycol in any specific amounts, much less in the proportions recited in the amended claims. Wood is therefore insufficient to support a rejection under 35 U.S.C. § 103(a). See In re Baird, 16 F.3d 380, 382 ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); MPEP § 2144.08.

Accordingly, for at least these reasons, the methods recited in the amended claims are not described, taught or suggested in Wood, and applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) based upon Wood is traversed based upon the amendments to the claims.

The Double Patenting Rejection

The Examiner has issued a provisional double patenting rejection citing four copending patent applications. Pursuant to MPEP § 804, if this is the sole remaining rejection prior to issuance of any of the copending applications as patents, this rejection should be withdrawn in this case. While Applicants do not admit that the claims of the present invention are obvious in view of any one of those copending applications, in the event that one or more of the copending applications issues as a patent prior to this application, Applicants will file a terminal disclaimer to obviate the double patenting rejection.

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes after considering these remarks, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

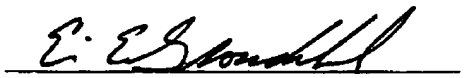
Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

No fee is believed to be required, as November 11, 2005 was a holiday and this paper is being filed on the first business day after that date. If any fee is required, or if

necessary to cover any deficiency in fees previously paid, authorization is hereby given to charge our Deposit Account No. 50-3569.

Respectfully submitted,

Date: November 14, 2005



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